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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,538

08/19/2005

Peter Forsell

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EXAMINER

GILBERT, SAMUEL G

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

06/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,538	Applicant(s) FORSELL, PETER	
	Examiner Samuel G. Gilbert	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-93 is/are pending in the application.
- 4a) Of the above claim(s) 33-57 and 65-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 32 and 58-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/27/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the species directed to a fatigue resistant layer in the reply filed on 3/24/2010 is acknowledged. Claims 31 and 32 are generic.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 32 and 58-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31- lines 8 and 9 appear to include inappropriate punctuation, periods. 5the claim must be written as a single sentence. The examiner is considering the entire claim for action on the merits.

Claim 32 - in line 2 it is unclear if "a layer or a coating" is the same as "a layer or a coating" set forth in claim 32.

Claim 60 - it is unclear if "said layer line 2 is referring to a "layer of the base or a layer of the property improving means. Because the claim is referring to a "silicone layer" which is only set forth in the base in claim 31, the examiner is considering the limitations of this claim to be directed to the base of the device.

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Claim 63 - it is unclear if “the hard silicone and polyurethane is intended to refer to the silicone and polyurethane set forth in claim 31, or additional material different from that recited previously.

Claim 64 - in line 3, it is unclear which “layer” is being referred to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 58-61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fierro (2002/0183588) in view of Stoy et al (4,480,642, hereinafter Stoy)).

Claim 31 - Fierro sets forth an implantable constriction device as shown in figure 3, including an elongate composite structure -2- formed from a self supporting base material, having a layer of silicone paragraph [0074], and a reinforcement layer element -9- formed from a polyester mesh the base including a property improving means comprising a layer -6- formed of “foamed silicone”, paragraphs [0055] and [0076] which is a different material from the silicone and polyester of the base. The property improving means, pad -6- is provided to improve the frictional property of the device, paragraph [0056]. The constriction device is capable of constricting a penile blood

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vessel. However, the claim requires the base to include layers of silicone and polyurethane not layers of silicone and polyester as taught by Fierro.

Stoy teaches a medical device formed from a hydrogel material and including reinforcement elements -12-. The reinforcement elements may be made from polyester or polyurethane, column 4 lines 45-50.

It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to select any material from the list material usable to make reinforcement elements as set forth in Stoy to make the reinforcement mesh of Fierro as an ordinary design choice to one of ordinary skill in the medical arts. The selection of any material from a list of known material to make the reinforcement elements would produce a predictable result because all the materials listed are used to form reinforcement elements and the selection would have a high expectation of success because the material is known in the art to form reinforcement elements.

Claim 32 - the property improving means is at least along the side of the base that is intended to contact the blood vessel as shown in figure 6.

Claim 58 - the foamed silicone, provides a device that is more "fatigue resistant" than said base material alone. The foam allows repeated compression and expansion while maintaining material strength that is not present in the silicone of the base material alone as an inherent function of foamed silicone.

Claim 59 - the property improving means is at least along the side of the base that is intended to contact the blood vessel as shown in figure 6.

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Claim 60 - the silicone -4- surrounds the reinforcement layer -9-, which may be made from polyurethane as set forth above.

Claim 61 - the property improvement means has better anti-friction properties as set forth in paragraph [0056].

Claim 63 - the material of the base is considered "hard" because the material is unyielding such that it is used to support the urethra.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Fierro and Stoy as applied to claim 31, 58 and 61 above, and further in view of Wijeratne et al (6,287,315, hereinafter Wijeratne).

Claim 62 - the combination teaches a device as claimed but does not set forth the use of the claimed material for the layer or coating property improving means.

The property improving means of the combination is directed to friction reducing material. Wijeratne teaches low-friction material including polyurethane, silicone or PTFE (polytetrafluoroethylene) may all be substituted for one another. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use polytetrafluoroethylene in place of the material for reducing friction as set forth in the combination as a substitution of functionally equivalent materials as shown by Wijeratne. Such a substitution would produce predictable results with a high expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 31, 32 and 58-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-12, 17-21, 23-27, 32-44, 53-60, 72-76 and 78-81 of copending Application No. 11/889,756. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modification in the scope of the claims. The intended use of the apparatus is different while the structure of the claimed device is almost identical differing in only inconsequential modifiers or slightly differing language.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/
Primary Examiner, Art Unit 3735